

REMARKS

Claims 1-60 and 105 are pending. Withdrawn Claims 61-104 have been cancelled.
Claims 16, 24, and 54 have been amended.

Applicant reminds the Examiner that as to the statutory double patenting rejection, "[i]f a 'provisional' statutory double patenting rejection is the only rejection remaining in both applications, the examiner should withdraw that rejection in the application with the earlier filing date and permit that application to issue as a patent." MPEP §804.B.2. The other double patenting rejections are either moot by amendment or can be resolved with a terminal disclaimer, if appropriate, once the claims are otherwise in condition for allowance.

The Office Action stated that the phrase "low molecular weight" was indefinite. To the contrary, Applicant notes that they have specifically defined "low molecular weight polymer" in the specification:

The term "low molecular weight (LMW) polymer" refers to bioerodible polymers having a weight average molecular weight ranging from about 3000 to about 10,000; preferably from about 3000 to about 9,000; more preferably from about 4000 to about 8,000; and more preferably the low molecular weight polymer has a molecular weight of about 7000, about 6000, about 5000, about 4000 and about 3000 as determined by gel permeation chromatography (GPC).

Applicant's specification (para. [0064]; emphasis added). Accordingly, "low molecular weight polymer" as recited in Claim 11 is not indefinite.

The Office Action objects to the phrase "miscibility in water of less than 7%." Applicant respectfully submits that an applicant may be his own lexicographer. Moreover, the meaning of the term is explained in the Applicant's specification, for example, *see* para. [0060].

Applicant is perplexed by the Office Action's request for clarification regarding "amount *effective* to plasticize the polymer and form a gel." The language is definite -

Applicants described an amount in terms of its effect. An amount of solvent that is insufficient to plasticize the polymer is not within the scope of the claim.

Regarding, "lower alkylene" the specification provides that "[t]he term "lower alkyl" intends an alkyl group of 1 to 6 carbon atoms, preferably 1 to 4 carbon atoms." *Id.* at [0068]. Those skilled in the art are aware of the meaning of the suffix "ene."

The examiner is incorrect in assuming that Independent Claims 2 and 29 require the solvent to be an aromatic alcohol, it is merely one possible selection from the Markush group: "a solvent selected from the group consisting of aromatic alcohols, esters of aromatic acids, aromatic ketones, and mixtures thereof." Thus, Claims 7-9 and 44-46 do, in fact, further limit their respective independent claims.

Applicant refers the Examiner to paras. [0080]-[0081] of the specification for a discussion of the phrase "lactic acid based polymer." Armed with this disclosure, one skilled in the art can easily discern the metes and bounds of the claimed invention.

The Office Action states that the phrase "analogs, derivatives, and fragments thereof" is indefinite. When the phrase is read in context, *i.e.*, with the entire claim, people skilled in the beneficial art are well aware of the bounds of the limitation. Drug analogs, derivatized drugs, and active fragments, as with peptides, are well known to those skilled in the art.

Applicant traverses the anticipation rejections based on WO 02/38185. **A proper anticipation rejection must teach all limitations.** The Examiner has failed to demonstrate that the references disclose a "solvent having miscibility in water of less than or equal to 7% at 25°C." Without this, the Examiner has failed to establish a *prima facie* case of anticipation.

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Applicant traverses the obviousness rejections based on WO 02/38185. Again, the Examiner has failed to demonstrate that the reference teaches or suggests a "solvent having miscibility in water of less than or equal to 7% at 25°C." While, the WO 02/38185 reference repeatedly recites "a biocompatible organic solvent that is miscible to dispersible in aqueous medium or body fluid," that is insufficient to render obvious a "solvent having miscibility in water of less than or equal to 7% at 25°C." The Examiner must provide evidence of the motivating force which would impel one skilled in the art to do what the Applicant has done. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness.

Applicant invites the Examiner to call the undersigned if he has questions.

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